DEC 22 2000

K003366

510(k) Summary of Safety and Effectiveness

Device Name	Phased Array Musculo-Skeletal Flex Coil Package (Model 545PH-64) consisting of the Phased Array Upper Extremity Flex Coil (Model 543PH-64) and the Phased Array Lower Extremity Flex Coil (Model 544PH-64)
Applicability	Compatible with Philips Gyroscan 1.5T MRI systems with Synergy (Phased Array) option
Reason for 510(k)	New device
Classification Name	Magnetic Resonance Diagnostic Device
Device Classification Panel	Radiology
Device Classification Number	892.1000
Product Code	90MOS
Common Name	Magnetic Resonance Specialty
Proprietary Name	Phased Array Musculo-Skeletal Flex Coil Package (Model 545PH-64) consisting of the Phased Array Upper Extremity Flex Coil (Model 543PH-64) and the Phased Array Lower Extremity Flex Coil (Model 544PH-64)
Establishment Registration Number	2183683
Address of MFG Facility	Device manufactured by: IGC-Medical Advances Inc. 10437 Innovation Drive Milwaukee, WI 53226 U.S.A.
Point of Contact	Michael J. Leigh Manager, Regulatory Affairs and Quality Assurance 414.258.3808 Ext. 206

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Classification	Class II	
Intended Uses		
Diagnostic Uses	2D, 3D imaging, proton density, T1 and T2 weighted imaging. 2D, 3D time of flight, phase contrast imaging.	
Anatomic Regions	Bones, soft tissue, musculo-skeletal structures and vascular structures in the upper and lower extremities	
Standards		
Performance Standards	None Established under Section 514	
Voluntary Safety Standards	UL 2601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
	UL 94	Tests for Flammability of Plastic Materials
	IEC 601-1	General Safety Requirements for Medical Electrical Equipment
	CPAI-84	Specification for Flame Resistant Material Used in Camping Tentage

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health (CDRH) released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. Due to considerable technological advances in MRDDs, CDRH issued an updated guidance document on November 14, 1998. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The Philips Gyroscan 1.5T MRI system operated with Phased Array Musculo-Skeletal Flex Coil Package is substantially equivalent to the same system operated with the legally marketed devices supplied by the OEM, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

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Safety Parameters

Maximum Static Magnetic Field:	No change
Rate of Magnetic Field Strength Change:	No change
RF Power Deposition:	No change
Acoustic Noise Levels:	No change
Biocompatibility:	No change

Imaging Performance Parameters

Specification Volume:	No change
Signal-to-Noise Ratio:	No change
Image Uniformity:	No change
Geometric Distortion:	No change
Slice Thickness and Gap:	No change
High Contrast Spatial Resolution:	No change

General Safety and Effectiveness Concerns

The device contains instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing. This information assures safe and effective use of the device.

Substantial Equivalence Summary

The Philips Gyroscan 1.5T MRI system operated with Phased Array Musculo-Skeletal Flex Coil Package addressed in this PMN, has the same intended use and technological characteristics as the same system operated with the legally marketed devices supplied by the OEM with the MR system. The use of these coils does not affect the Philips Gyroscan system safety parameter specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2002

R. Jerry Frohlich, P.E.
Manager, Quality Assurance and Regulatory Affairs
IGC Medical Advances
10437 Innovation Drive
MILWAUKEE WI 53226

Re: K003366
Trade/Device Name: Model 545PH-64 Phased Array Musculoskeletal Flex Coil Package with Model 855PH Synergy MultiConnect
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: 90 - MOS
Dated: October 27, 2000
Received: October 30, 2000

Dear Mr. Frohlich:

This letter corrects our substantially equivalent letter of December 22, 2000 regarding the omission of the Model 855PH Synergy MultiConnect from the Trade/Device Name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K003366

Device Name: Model 545PH-64: Phased Array Musculo-Skeletal Flex Coil Package with Model 855PH Synergy MultiConnect

Indications for Use:

Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of bones, soft tissue, musculo-skeletal structures and vascular structures in the upper and lower extremities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003366

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)